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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KELLY, ROBERT M

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/057,409

Applicant(s)

PALASIS, MARIA

Examiner

Robert M. Kelly

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 4-54 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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DETAILED ACTION

Applicant's response and amendments of 2/7/05 are entered.

Claims 1-3 are cancelled.

Claims 15, 17, 19, 21, 38, and 54 are amended.

Claims 4-54 are presently pending.

Examiner Reassignment

The Examiner assigned to prosecute this Application has changed to Robert M. Kelly, of Art Unit 1632 in Group 1630, Technology Center 1600. Future correspondence should be addressed to the new Examiner. Note that the Art Unit, Group and Technology Center remain unchanged.

Restriction Requirement

It is noted that the prior restriction requirement of 12/22/03 was improper because it does not follow proper linking-claim practice per MPEP 803, et seq. Therefore, the following restriction is held on the claims as currently pending. Upon election of a new group and species required, Applicant will receive another non-final action. It is further noted that Applicant should elect all species, even though a particular species may not pertain to an elected invention.

Second, it is noted that, due to the cancellation of claims 1-3 in the amendments of 2/7/05, certain claims, which were withdrawn are no longer interpretable. Those claims (i.e., 4-14) will be interpreted to incorporate the limitations of cancelled claim 1.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 4-5, 23-30, 36-37, 39-42, 52-53, and 54, drawn to methods requiring the delivery of proteins to myocardial tissue, classified in class 530, subclass 350.
- II. Claims 6-7, 9-11, 16, 18, 20, 22-27, 31-35, 39-40, 43-44, 46-48, 52-53, and 54, drawn to methods requiring the delivery of nucleic acids encoding proteins to a myocardial tissue, classified in class 514, subclass 44.
- III. Claims 6, 8, 43, 45, and 54, drawn to methods requiring the delivery of antisense nucleic acids to myocardial tissue, classified in class 536, subclass 24.5.
- IV. Claims 12-14, 23-25, 49-51, and 54, drawn to methods requiring the delivery of cells to myocardial tissue, classified in class 424, subclass 93.1.

The inventions are distinct, each from the other because of the following reasons:

Groups I-IV are patentably distinct. Inventions are patentably distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and have different structural and functional considerations (i.e., modes of operation) that would pose a serious burden on the examiner to search and examine any two groups together. To wit, Group I requires the administration of proteins, Group II requires the administration of nucleic acids, Group III requires the administration of antisense molecules, and Group IV requires the administration of cells, to myocardial tissue. Each of these compositions acts differently such that they would require different, non-coextensive considerations. To wit, the proteins must be administered and reach their site of action in large enough quantities for a long enough period of time to effect the

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claimed treatments, nucleic acids encoding proteins must enter cells, become incorporated, be transcribed, translated and the proteins must then reach the site of action in large enough quantities for a long enough period of time to effect the claimed treatments. The antisense molecules, similar to the nucleic acids must enter the cells and either become incorporated and transcribed to produce molecules which enter, or they must directly enter, the cellular pathways to inhibit the transcription or translation of another molecule. Lastly, the cells must enter the body, enter the tissue required, become part of that tissue, and produce enough of an effect for a long enough period of time to effect treatment. Because of these different structures therefore, the function of each of these are distinct, and non-coextensive. Each of these molecules therefore have the required different modes of operation to meet the requirements of restriction.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Claims 15, 17, 23-24, 49-51, and 54 link(s) inventions I-IV. The restriction requirement of the linked inventions is subject to the nonallowance of the linking claim(s), claims 15, 17, 19, 21, and 38. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant

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application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

This application contains claims directed to the following patentably distinct species of the claimed invention:

(1) Applicant is required to choose one of the 14 proteins listed in claims 19 species of protein listed in claims 5, 7, 25, 27, 37, 42, and 44 (it is noted that Applicant also claims other genera in the form of a species, like growth factor, endothelial growth factor, and vascular smooth muscle growth factor, but these are considered to overlapping generas and not specific species, hence, the election of a species does not include these genera);

(2) Applicant is required to choose one of the 6 promoters listed in claims 30 and 32; and

(3) Applicant is required to choose one of the 6 cell types from claims 13 and 50.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 4, 6, 12, 15-24, 26, 28-29, 31, 38, 41, 43, and 49 generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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